
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event Reported): January 31, 2018

BEIGENE, LTD.

(Exact Name of Registrant as Specified in Charter)

Cayman Islands

(State or Other Jurisdiction of Incorporation)

001-37686

(Commission File Number)

98-1209416

(I.R.S. Employer Identification Number)

c/o Maurant Ozannes Corporate Services (Cayman) Limited

94 Solaris Avenue, Camana Bay

Grand Cayman KY1-1108

Cayman Islands

(Address of Principal Executive Offices) (Zip Code)

+1 (345) 949 4123

(Registrant's telephone number, including area code)

Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events.

On January 31, 2018, BeiGene, Ltd. (the “Company”) issued a press release announcing that the first patient was dosed in a global Phase 3 clinical trial of tislelizumab, an investigational anti-PD-1 antibody, as a potential second-line treatment in patients with advanced unresectable or metastatic esophageal squamous cell carcinoma (ESCC). The full text of this press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued on January 31, 2018

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued on January 31, 2018

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

BEIGENE, LTD.

Date: January 31, 2018

By: /s/ Scott A. Samuels

Scott A. Samuels

Senior Vice President, General Counsel

BeiGene Initiates Global Phase 3 Trial of Anti-PD-1 Antibody Tislelizumab in Patients with Esophageal Squamous Cell Carcinoma

CAMBRIDGE, Mass. and BEIJING, China, Jan. 31, 2018 (GLOBE NEWSWIRE) -- BeiGene, Ltd. (NASDAQ:BGNE), a commercial-stage biopharmaceutical company focused on developing and commercializing innovative molecularly targeted and immuno-oncology drugs for the treatment of cancer, today announced that the first patient was dosed in a global Phase 3 clinical trial of tislelizumab, an investigational anti-PD-1 antibody, as a potential second-line treatment in patients with advanced unresectable or metastatic esophageal squamous cell carcinoma (ESCC). Tislelizumab is also being studied in global Phase 3 trials in non-small cell lung cancer and hepatocellular carcinoma and two pivotal Phase 2 trials in China in relapsed/refractory classical Hodgkin lymphoma and urothelial cancer.

“We are pleased to be leading the third global Phase 3 study of tislelizumab under our strategic collaboration with Celgene. These studies are designed to support regulatory filings both in China and globally, and take advantage of our unique global clinical development organization as well as the recent regulatory reforms in China. In 2018, we look forward to further expanding the development program for tislelizumab and to accomplishing key milestones including a planned NDA submission in China,” commented John V. Oyler, Founder, Chief Executive Officer, and Chairman of BeiGene.

“Patients with advanced unresectable or metastatic esophageal carcinomas face poor prognosis, especially those with squamous histology, due to the extremely aggressive nature of the disease. We are hopeful that this Phase 3 trial will establish safety and efficacy of tislelizumab as an important treatment option for these patients,” commented Amy Peterson, M.D., Chief Medical Officer, Immuno-Oncology, at BeiGene.

The Phase 3, open-label, multi-center, randomized trial is designed to compare the efficacy and safety of tislelizumab compared to investigator-chosen chemotherapy as a second-line treatment in patients with advanced unresectable or metastatic ESCC. Approximately 450 patients are planned to be enrolled in Greater China, Japan, Korea, Belgium, France, Germany, Italy, Spain, the United Kingdom and the United States. Patients will be randomized to receive either tislelizumab at 200 mg every three weeks or one of three single-agent chemotherapies, paclitaxel, docetaxel, or irinotecan, as determined by the investigator.

The trial’s primary endpoint is overall survival, and secondary endpoints include progression-free survival, objective response rate, duration of response, health-related quality of life, safety, and tolerability.

“Treatment options for esophageal squamous cell carcinoma have been limited to chemotherapy. Tislelizumab has shown promising anti-tumor activity and has been generally well-tolerated in clinical trials to date in patients with a variety of cancers, including esophageal cancer, and we are hopeful that data from this Phase 3 trial will lead to a new treatment option where it is so greatly needed,” said Professor Lin Shen, M.D., Vice President at the Beijing Cancer Hospital, Beijing, China, and lead investigator of the trial.

For more information about the trial, patients and physicians should email BeiGene at BGBA317clinicaltrials@beigene.com.

About Esophageal Squamous Cell Carcinoma

Esophageal cancer, which includes squamous cell carcinoma, is considered a serious malignancy with respect to prognosis and a fatal outcome in the great majority of cases. Esophageal carcinoma affects more than 450,000 people worldwide. ⁱ Esophageal cancer is the eighth most common cancer worldwide and the sixth most common cause of death from cancer. ⁱⁱ

Esophageal squamous cell carcinoma occurs at a rate 20 to 30 times higher in China than in the United States. ⁱ An esophageal “cancer belt,” primarily squamous cell cancers, extends from northeast China to the Middle East. ⁱ Advanced esophageal cancer is a rapidly fatal disease. More than two-thirds of patients diagnosed with esophageal cancer will have advanced or metastatic disease, with a median survival of 8-10 months and an expected five-year survival rate of less than five percent. ⁱⁱⁱ These data, combined with the relative lack of highly effective treatment, are indicative of the large unmet medical need in patients diagnosed with esophageal cancer.

About Tislelizumab (BGB-A317)

Tislelizumab is an investigational humanized monoclonal antibody that belongs to a class of immuno-oncology agents known as immune checkpoint inhibitors. It is designed to bind to PD-1, a cell surface receptor that plays an important role in downregulating the immune system by preventing the activation of T-cells. Tislelizumab has demonstrated high affinity and specificity for PD-1. It is differentiated from the currently approved PD-1 antibodies in an engineered Fc region, which is believed to minimize potentially negative interactions with other immune cells. Tislelizumab is being developed as a monotherapy and in combination with other therapies for the treatment of a broad array of both solid tumor and hematologic cancers. BeiGene and Celgene Corporation have a global strategic collaboration for tislelizumab for solid tumors outside of Asia (except Japan).

About BeiGene

BeiGene is a global, commercial-stage, research-based biotechnology company focused on molecularly targeted and immuno-oncology cancer therapeutics. With a team of over 850 employees in China, the United States, and Australia, BeiGene is advancing a pipeline consisting of novel oral small molecules and monoclonal antibodies for cancer. BeiGene is also working to create combination solutions aimed to have both a meaningful and lasting impact on cancer patients. BeiGene markets ABRAXANE[®] (nanoparticle albumin-bound paclitaxel), REVLIMID[®] (lenalidomide), and VIDAZA[®] (azacitidine) in China under a license from Celgene Corporation. ^{iv}

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding BeiGene’s advancement of, and anticipated clinical development, regulatory milestones and commercialization of tislelizumab. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including BeiGene’s ability to demonstrate the efficacy and safety of its drug candidates; the clinical results for its drug candidates, which may not support further development; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials; BeiGene’s ability to achieve market acceptance

in the medical community necessary for commercial success; BeiGene's ability to obtain and maintain protection of intellectual property for its technology and drugs; BeiGene's reliance on third parties to conduct drug development, manufacturing and other services; BeiGene's limited operating history and BeiGene's ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates, as well as those risks more fully discussed in the section entitled "Risk Factors" in BeiGene's most recent quarterly report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in BeiGene's subsequent filings with the U.S. Securities and Exchange Commission. All information in this press release is as of the date of this press release, and BeiGene undertakes no duty to update such information unless required by law.

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ⁱ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3769895/>

ⁱⁱ GLOBOCAN, 2012 <http://globocan.iarc.fr>

ⁱⁱⁱ Parkin, 1999; Lin M, 2016; Drahos J, 2013.

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